

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 20 1995

Sally L. Van Wert, Ph.D.
Manager, Regulatory Affairs - Biotechnology
AgrEvo USA Company
Little Falls Centre One
2711 Centerville Road
Wilmington, DE 19808

Dear Dr. Van Wert:

This is in regard to your genetically modified glufosinate tolerant canola (HCN92) about which you initiated consultations with the agency in October, 1994. The new canola variety has been rendered tolerant to glufosinate by expression of a synthetic version of a phosphinothricin-N-acetyltransferase gene derived from *Streptomyces viridochromogenes*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new canola variety. On March 17, 1995, you also made a detailed oral presentation of the data that support your submission. It is our understanding that these communications were intended by AgrEvo to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Further, based on the safety and nutritional assessment you have conducted, it is our understanding that you have concluded, in essence, that the new canola variety is not significantly altered in composition, safety, or any other relevant parameter from canola varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 000023 and that will be maintained in the Office of Premarket Approval.

Based on the description of the data and information presented during the consultation, the new canola variety does not appear to be significantly altered within the meaning of 21 CFR 170.30(f)(2).

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We have no additional questions concerning this product at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

CC: HFS-200 HFS-205 HFS-206 HFS-226 HFS-246 HFS-247 HFS-013
HFV-221 BNF000023